

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Verrier *et al.*Appl. No.: *To Be Assigned (Div. of Appl.
No. 09/769,439; Filed: January 26, 2001)*

Filed: Herewith (January 23, 2004)

For: **Kit for Transvenously Accessing
the Pericardial Space Via the Right
Atrium**Confirmation No.: *To Be Assigned*Art Unit: *To Be Assigned*Examiner: *To Be Assigned*

Atty. Docket: 1565.0020003/MBR/GSB

Information Disclosure StatementCommissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may

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not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

Applicants have checked the appropriate boxes below.

- ☐ 1. Statement under 37 C.F.R. 1.704(d). Each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this information disclosure statement.
- ☒ 2. Filing under 37 C.F.R. § 1.97(b). This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits OR before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No statement or fee is required.
- ☐ 3. Filing under 37 C.F.R. § 1.97(c). This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application.

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- ☐ a. Statement under 37 C.F.R. § 1.97(e)(1). I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
- ☐ b. Statement under 37 C.F.R. § 1.97(e)(2). I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐ c. Attached is our PTO-2038 Credit Card Payment Form in the amount of \$_____ in payment of the fee under 37 C.F.R. § 1.17(p).
- ☐ 4. Filing under 37 C.F.R. § 1.97(d) This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. Enclosed find our PTO-2038 Credit Card Payment Form in the amount of \$_____ in payment of the fee under 37 C.F.R. § 1.17(p); in addition:
- ☐ a. Statement under 37 C.F.R. § 1.97(e)(1). I hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign

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application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).

- ☐ b. Statement under 37 C.F.R. § 1.97(e)(2). I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐ 5. The document(s) was/were cited in a search report by a foreign patent office in a counterpart foreign application. Submission of an English language version of the search report that indicates the degree of relevance found by the foreign office is provided in satisfaction of the requirement for a concise explanation of relevance. 1138 OG 37, 38.
- ☐ 6. A concise explanation of the relevance of the non-English language document(s) appears below:
- ☐ 7. Copies of the documents are submitted herewith.
- ☒ 8. Copies of the documents were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/769,439, filed January 26, 2001, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

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It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO 1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



George S. Bardmesser
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Date: January 23, 2004

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FORM PTO-1449				ATTY. DOCKET NO. 1565.0020003/MBR/GSB		APPLICATION NO. To Be Assigned	
INFORMATION DISCLOSURE STATEMENT				FIRST NAMED INVENTOR Richard L. VERRIER		FILING DATE Herewith (January 23, 2004)	
				ART UNIT To Be Assigned			
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE	
	AA1	6,179,816	01/2001	Mottola <i>et al.</i>	604	264	
	AB1	6,162,195	12/2000	Igo <i>et al.</i>	604	164	
	AC1	5,968,010	10/1999	Waxman <i>et al.</i>	604	49	
	AD1	5,941,869	08/1999	Patterson <i>et al.</i>	604	508	
	AE1	5,725,512	03/1998	Swartz <i>et al.</i>	604	280	
	AF1	5,722,972	03/1998	Power <i>et al.</i>	606	7	
	AG1	5713849	02/1998	Bosma <i>et al.</i>	604	28	
	AH1	5,569,197	10/1996	Helmus <i>et al.</i>	604	96	
	AI1	5,554,114	09/1996	Wallace <i>et al.</i>	604	53	
	AJ1	5,476,450	12/1995	Ruggio	604	93	
	AK1	5354279	10/1994	Hofling	604	164	
FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY PCT	CLASS	SUB-CLASS	TRANSLATION	
	AL1	WO 98/48881	11/1998			Yes No	
	AM1					Yes No	
	AN1					Yes No	
	AO1					Yes No	
	AP1					Yes No	
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)							
AR	1	Avitall, B. <i>et al.</i> , "A New Technique For AV Nodal Modification Using Pernodal Injection Of A Sclerosing Agent", JACC, Vol. 17, No. 2, February, 1991, pg. 174A. (Abstract only)					
AS	1	Avitall, B. <i>et al.</i> , "Iontophoretic Transport of Procainamide and D-Sotalol Into Arrhythmogenic Myocardium: Efficacy in Ventricular Tachycardia Suppression", JACC, Vol. 17, No. 2, February, 1991, pg. 39A. (Abstract only)					
AT	1	Avitall, B. <i>et al.</i> , "Iontophoretic Delivery of Dobutamine: An Effective Method To Increase Contractility of Non-Transmural Infarcts", JACC, Vol. 17, No. 2, February 1991, pg. 27A. (Abstract only)					
EXAMINER /Manuel Mendez/				DATE CONSIDERED 10/23/2008			
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.							

FORM PTO-1449				ATTY. DOCKET NO. 1565.0020003/MBR/GSB FIRST NAMED INVENTOR Richard L. VERRIER		APPLICATION NO. To Be Assigned		Page 2 of 6
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U.S. PATENT DOCUMENTS								
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE	
	AA2	5,269,326	12/1993	Verrier	128	642		
	AB2	5,147,336	09/1992	Wendell <i>et al.</i>	604	283		
	AC2	5,137,510	08/1992	VanDeripe	604	28		
	AD2	5,092,848	03/1992	deClutis	604	170		
	AE2	5,033,477	07/1991	Chin <i>et al.</i>	128	785		
	AF2	4,998,975	03/1991	Cohen <i>et al.</i>	128	419D		
	AG2	4,991,603	02/1991	Cohen <i>et al.</i>	128	786		
	AH2	4,991,578	02/1991	Cohen	128	419D		
	AI2	4,961,731	10/1990	Bodicky <i>et al.</i>	604	264		
	AJ2	4,946,457	08/1990	Elliott	606	1		
	AK2	4,884,567	12/1989	Elliott <i>et al.</i>	128	303R		
FOREIGN PATENT DOCUMENTS								
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION	
	AL2						Yes No	
	AM2						Yes No	
	AN2						Yes No	
	AO2						Yes No	
	AP2						Yes No	
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)								
	AR	2	Baim, Donald S. <i>et al.</i> , "Cardiac Catheterization, Angiography, and Intervention", Fifth Edition, <i>Williams and Wilkins Publishing</i> , U.S.A., 1996, pp. 809-813.					
	AS	2	Brockenbrough <i>et al.</i> , "A New Technic for Left Ventricular Angiocardiography and Transseptal Left Heart Catheterization", <i>The American Journal of Cardiology</i> , December 1960, pp. 1062-1064.					
	AT	2	Buselmeier, T.J. <i>et al.</i> , "Treatment of Intractable Uremic Pericardial Effusion: Avoidance of Pericardiectomy with Local Steroid Instillation", <i>Journal of the American Medical Association</i> , Vol. 240, No. 13, 1978, pp. 1358-1359.					
EXAMINER					DATE CONSIDERED			
/Manuel Mendez/					10/23/2008			
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U.S. PATENT DOCUMENTS								
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE	
	AA3	4,865,037	09/1989	Chin <i>et al.</i>	128	419D		
	AB3	4,769,016	09/1988	Labianca	604	280		
	AC3	4,765,341	08/1988	Mower <i>et al.</i>	128	785		
	AD3	4,717,387	01/1988	Inoue <i>et al.</i>	604	264		
	AE3	4,708,145	11/1987	Tacker, Jr. <i>et al.</i>	128	419D		
	AF3	4,699,147	10/1987	Chilson <i>et al.</i>	128	642		
	AG3	4,619,247	10/1986	Inoue <i>et al.</i>	128	6		
	AH3	4,567,900	02/1986	Moore	128	784		
	AI3	4,319,562	03/1982	Crosby	128	1R		
	AJ3	4,296,100	10/1981	Franco	424	108		
	AK3	4,292,976	10/1981	Banka	128	656		
FOREIGN PATENT DOCUMENTS								
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION	
	AL2							Yes
	AM2							No
	AN2							Yes
	AO2							No
	AP2							Yes
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)								
	AR	3	DiCarlo, S.E. <i>et al.</i> , "Exercise Training Enhances Cardiac Afferent Inhibition of Baroreflex Function", <i>The American Physiological Society</i> , Order No. 0363-6135, 1990, pp. H212-H220.					
	AS	3	Dorward, P.K. <i>et al.</i> , "Blockade of Cardiac Nerves By Intrapericardial Local Anesthetics In The Conscious Rabbit", <i>Aust. J. Exp. Biol. Med. Sci.</i> , Vol. 61 (Pt. 2), 1983, pp. 219-230.					
	AT	3	Miyazaki T. <i>et al.</i> , "Prostaglandins in the Pericardial Fluid Modulate Neural Regulation of Cardiac Electrophysiological Properties", <i>Circulation Research</i> , Vol. 66, No. 1, January 1990, pp. 163-175.					
EXAMINER					DATE CONSIDERED			
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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT		ATTY. DOCKET NO. 1565.002003/MBR/GSB FIRST NAMED INVENTOR Richard L. VERRIER FILING DATE Herewith (January 23, 2004)	APPLICATION NO. To Be Assigned ART UNIT To Be Assigned
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U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA4	4,256,115	03/1981	Billitch	128	419P	
	AB4	4,181,123	01/1980	Crosby	128	6	
	AC4	4,173,981	11/1979	Mortensen	128	348	
	AD4	4,146,029	03/1979	Ellinwood, Jr.	128	260	
	AE4	4,003,379	01/1977	Ellinwood, Jr.	128	260	
	AF4	3,680,544	08/1972	Shinnick et al.	128	2R	
	AG4	3,630,207	12/1971	Kahn et al.	128	350R	
	AH4						
	AI4						
	AJ4						
	AK4						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL4						Yes
	AM4						No
	AN4						Yes
	AO4						No
	AP4						Yes
							No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>4</u>	Miyazaki, T. <i>et al.</i> , "Presynaptic Modulation of Efferent Sympathetic and Vagal Neurotransmission in the Canine Heart by Hypoxia, High K ⁺ , Low pH, and Adenosine", <i>Circulation Research</i> , Vol. 66, No. 2, February, 1990, pp. 289-301.
	AS	<u>4</u>	Uchida <i>et al.</i> , "Angiogenic Therapy of Acute Myocardial Infarction by Intrapericardial Injection of Basic Fibroblast Growth Factor and Heparin Sulfate: an Experimental Study", <i>American Heart Journal</i> , Vol. 130, No. 6, December, 1995, Pages 1182-1188.
	AT	<u>4</u>	Verrier, R. L., <i>et al.</i> , "Protective Zone and The Determination of Vulnerability to Ventricular Fibrillation", <i>The American Physiology Society</i> , 1978, Order No. 0363-6135/78/0000-0000, pp. H592-H596.

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INFORMATION DISCLOSURE STATEMENT							
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
		AA5					
		AB5					
		AC5					
		AD5					
		AE5					
		AF5					
		AG5					
		AH5					
		AI5					
		AJ5					
		AK5					
FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
		AL5					Yes
		AM5					No
		AN5					Yes
		AO5					No
		AP5					Yes
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)							
	AR	5	Verrier, R.L. <i>et al.</i> , "Prevention of Ventricular Fibrillation by Use of Low-Intensity Electrical Stimuli", Reprinted from <i>The Annals of the New York Academy of Sciences</i> , 1982, pp. 355-370.				
	AS	5	Verrier, R.L. <i>et al.</i> , "Transatrial Access to the Normal Pericardial Space-A Novel Approach for Diagnostic Sampling, Pericardiocentesis, and Therapeutic Interventions", <i>Circulation: Journal of American Heart Association</i> , on or about December 8, 1998 (based on information presently available), pp. 2331-2333.				
	AT	5	Welt et al., "Second International Symposium on Cardiovascular Drug Delivery", <i>Circulation, American Heart Association</i> , Vol. 95, No. 4, February 18, 1997, pp. 773-776.				
EXAMINER /Manuel Mendez/					DATE CONSIDERED 10/23/2008		
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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT				ATTY. DOCKET NO. 1565 002003/MBR/GSB FIRST NAMED INVENTOR Richard L. VERRIER FILING DATE Herewith (January 23, 2004)		APPLICATION NO. To Be Assigned ART UNIT To Be Assigned		Page 6 of 6
U.S. PATENT DOCUMENTS								
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE	
	AA6							
	AB6							
	AC6							
	AD6							
	AE6							
	AF6							
	AG6							
	AH6							
	AI6							
	AJ6							
	AK6							
FOREIGN PATENT DOCUMENTS								
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION	
	AL6							Yes
	AM6							No
	AN6							Yes
	AO6							No
	AP6							Yes
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)								
	AR	6	International Search Report from PCT Appl. No. PCT/US00/07444, 5 pages, mailed July 12, 2000.					
	AS	6						
	AT	6						
EXAMINER /Manuel Mendez/					DATE CONSIDERED 10/23/2008			
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